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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/602,272	02/16/1996	MICHAEL J. ELLIOTT	KIR96-01	4297

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
07/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/602,272	ELLIOTT ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 6,9,10,12-15,37,51 and 53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 6,9,10,12-15,37 and 53 is/are rejected.

7)☐ Claim(s) 51 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16, 2007 has been entered.

Claims 29, 31, 32, 34-36 and 52 have been canceled. Claim 6 has been amended. Claim 53 has been added. Claims 6, 9, 10, 12-15, 37, 51 and 53 are pending and under consideration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how claim 51 further limits the scope of claim 6. Claim 6 specifies "wherein the thrombosis is deep vein thrombosis". there is no antecedent basis in claim 6 for a thrombosis other than a deep vein thrombosis. Amendment of claim 51 to recite "wherein the thombotic disorder is deep vein thrombosis" would overcome this rejection.

The recitation of "cardiovascular disorder" in claim 53 lacks antecedent basis in claim 6 which limits the thrombotic disorders to thromboembolic, ischemia, stroke, acute myocardial infarction, DVT and thrombophlebitis, and thus "cardiovascular disorder" is outside the scope of the thrombotic disorders listed in claim 6.

Claim 37 is vague and indefinite because it depends on a canceled claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by the abstract of Squadrito et al (European Journal of Pharmacology, 1993, Vol. 237, pp, 223-230).

Claim 6 is drawn to a method of treating a thrombotic disorder in a subject in need thereof comprising administering a therapeutically effective amount of an anti-TNF antibody or antigen-binding fragment thereof to said subject, wherein the thrombotic disorder includes an ischemic event and acute myocardial infarction. Claim 53 specifies that the cardiovascular disorder includes acute myocardial infarction.

Squadrito et al disclose a method of treating acute myocardial necrosis which is the same as myocardial infarction, said necrosis due to an ischemic event in experimental rats, by the administration of anti-TNF antibodies.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the abstract of Strieter et al (Critical Care Medicine, 1993, 21(10 suppl):S447-S463).

The abstract teaches that a synthesis of literature data from 1975 indicates that TNF influences the outcome of ischemia-reperfusion injury, and that administration of anti-TNF antibodies may limit organ damage induced by TNF and reduce mortality rates.

It would have been prima facie obvious at the time the claimed invention was made to treat a ischemic event by the administration of anti-TNF antibodies. One of skill in the art would have been motivated to do so by the suggestion of the abstract of Strieter that administration of such antibodies can reduce organ damage and mortality in ischemic-reperfusion injury.

Claims 6, 9, 10-15, 37 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le et al (US 5,656,272, cited in a previous Office action) in view of Bender et al (U.S. 5,317,019).

Le et al teach a method for treating a TNFalpha mediated disease in a human comprising the administration of a chimeric anti-TNF antibody which bind to residues 87-108 and 59-80 in human TNF and the cA2 antibody (column 5, lines 36-47 and column 7, lines 10-25). Le et al do not teach the treatment of a TNFalpha mediated disease which is myocardial infarction or stroke by the administration of the cA2 antibody..

Bender et al teach that tissue injury associated with myocardial infarction and stoke is mediated by TNF (column 21, lines 20-25).

It would have been prima facie obvious at the time the claimed invention was made to substitute myocardial infarction or stoke for the TNFalpha mediated disease as taught by Le et al. One of skill in the art would have been motivated to do so by the teachings of Bender which identify myocardial infarction and stroke and TNFalpha mediated diseases. Further, the cA2 antibody would have the property of competitively inhibiting the binding of TNFalpha to cA2, thus fulfilling the limitation of claim 15.

Claims 6, 9, 10-15, 37 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Le et al and Bender et al as applied to claims 6, 9, 10-15, 37 and 53 above, and further in view of Naughton et al (U.S. 5,863,531).

Claim 6 further comprises the thrombotic disorder of thromboembolism.

Naughton et al teach that the presence of anti-TNF antibodies can prevent thromboembolism (column 5, lines 4-12).

It would have been prima facie obvious to substitute thromboembolism for the TNF mediated diseases taught by Bender et al by using the antibodies of Le et al. One of skill in the art would have been motivated to do so by the suggestion of Naughton et al that thromboembolism is a TNF-mediated disease.

Claim 51 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella/
Ph.D., Primary Examiner,
Art Unit 1643